K093018
page 1/2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

OCT - 7 2009

a. Company Name:	USGI Medical
b. Company Address:	1140 Calle Cordillera San Clemente, CA 92673
c. Telephone: Fax:	(949) 369-3890 (949) 369-3891
d. Contact Person:	Mary Lou Mooney Vice President of Clinical, Regulatory & Quality
e. Date Summary Prepared:	September 3, 2009

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	g-Prox Endoscopic Grasper
b. Common Name:	Grasper
c. Classification Name:	Gynecologic laparoscope and accessories, 884.1720

3. IDENTIFICATION OF PREDICATE DEVICES

g-Prox Endoscopic Grasper	USGI Medical (K061276)

K093018
page 2/2

4. DESCRIPTION OF THE DEVICE

The g-Prox Endoscopic Grasper is a sterile, single patient use device used for tissue grasping and mobilization. It includes a lumen that can accept the g-Cath Tissue Anchor Delivery Catheter and other small diameter instruments.

5. STATEMENT OF INTENDED USE

The g-Prox Endoscopic Grasper is intended for use in minimally invasive procedures to facilitate tissue grasping and mobilization.

6. COMPARISON WITH PREDICATE DEVICES

The g-Prox Endoscopic Grasper is comparable to the predicate devices in terms of intended use, technology, and materials.

Bench testing was conducted to ensure that the modified device performs as intended when used according to its instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

USGI Medical
% Ms. Mary Lou Mooney
VP of Clinical, Regulatory
& Quality
1140 Calle Cordillera
San Clemente, California 92673

OCT - 7 2009

Re: K093018
Trade/Device Name: g-Prox Endoscopic Grasper
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT, GDW, HET
Dated: September 3, 2009
Received: September 8, 2009

Dear Ms. Mooney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

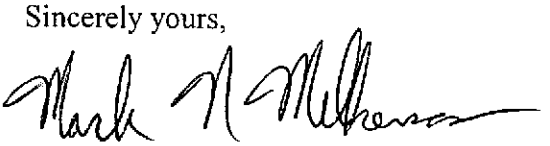
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093018

Device Name: g-Prox Endoscopic Grasper

Indications For Use:

The USGI g-Prox Endoscopic Grasper is intended for use in minimally invasive procedures to facilitate tissue grasping and manipulation.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093018